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DUPLOSPRAY MIS REGULATOR



Before using this device, read the following information
Review Applicator Instructions for Use for additional information, warnings and precautions.

INTENDED USE

The DUPLOSPRAY MIS Regulator is a re-usable, non-sterile device intended for regulating gas flow of medical grade vaporous carbon dioxide to assist in the application of Baxter surgical sealants.

CONTRAINDICATIONS

None

WARNINGS/PRECAUTIONS

The user should be familiar with the contents of these instructions prior to using the device.

Regulator should only to be used with DUPLOSPRAY MIS Applicators.

Only qualified personnel should operate this device.

Caution must be used when applying product using pressurized gas.

- Air or gas embolism has occurred with the use of spray devices employing pressure regulator to administer fibrin sealants. This event appears to be related to the use of the spray device at higher than recommended pressures and in close proximity to the tissue surface. When applying sealants using a spray device, be sure to use the flow rate recommended in the Instruction for Use.
- To avoid possible gas embolism, do not spray directly into circulatory pathways. Any application of pressurized gas is associated with a potential risk of air embolism, tissue rupture or gas entrapment with compression, which may be life threatening.

Be sure to take appropriate measures to address these risks by observing these recommendations:

Flow Rate	1.0 - 2.0 Liters per minute (L/min)		
Distance	2cm	3cm	5cm
		recommended	

- When using pressurized spray devices, changes in blood pressure, pulse, oxygen saturations, and end tidal CO₂ should be monitored because of the possibility of occurrence of air gas embolism.

Connect to regulated CO₂ gas source only.

Supply pressure to device shall be set to 100 psi $\pm$ 5 (6.89 bar $\pm$.35) and at a flow rate of 10 L/min minimum.

Do not expose to temperatures below -4 °F (-20°C) , above 122 °F (50°C) , or to relative humidity (RH) above 95%.

Do not immerse or soak any part of the device.

Review Section #5 and #6 for additional information regarding cleaning, maintenance and other vital information for use.

1.0 DESCRIPTION OF OPERATION

The DUPLOSPRAY MIS Regulator is a reusable, non-sterile device consisting primarily of a gas pressure regulator, flow control valve, flow meter and a foot switch. The internal pressure regulator is a fixed-output device that reduces 100psi $\pm$ 5 (6.89 bar $\pm$.35) incoming supply gas pressure to the device to a preset 19psi $\pm$ 2 (1.31 bar $\pm$.13) output pressure. A safety relief valve inside the Regulator ensures a maximum output limit of 22 psi (1.5 bar) cannot be exceeded. The safety relief valve will safely vent inside the housing at pressures above 22 psi (1.5 bar) with an audible signal. The pressure relief valve will reset automatically when the over pressure condition is removed.

1.1 CONTENTS OF CARTON

- Regulator assembly (including pre-mounted pole clamp) with Foot switch, and a Gas (DISS Female CO₂) Connection.

2.0 SET UP

Conditions: 55°F (13°C) to 80°F (27°C), 0% to 60% RH

The DUPLOSPRAY MIS Regulator comes with a pre-mounted Pole Clamp (7) that can be used to mount device onto a stable pole.

2.1 SET UP REGULATOR

- Attach Gas (DISS Female CO₂) Connection (1) to CO₂ gas source and set gas supply pressure to 100psi $\pm$ 5 (6.89 bar $\pm$.35).

2.2 FOOT SWITCH

- Place Foot Switch (2) flat in convenient location.

3.0 FUNCTIONAL CHECK

During first time use and minimally on a semi-annual basis, conduct a functional check.

3.1 VERIFY REGULATOR FLOW

- While depressing Foot Switch (2), turn Flow Control Knob (6), clockwise and back and verify flow is adjustable from 0 to 10 L/min minimum as indicated by the Flow Meter (4).
- While depressing Foot Switch (2), turn Flow Control Knob, (6), clockwise and adjust flow to 1.5 L/min as indicated on Flow Meter (4).
- With foot switch (2) released verify flow control ball does not stick at top of Flow Meter (4).
- Note: After successfully performing above procedure, the DUPLOSPRAY MIS Regulator is ready for use.

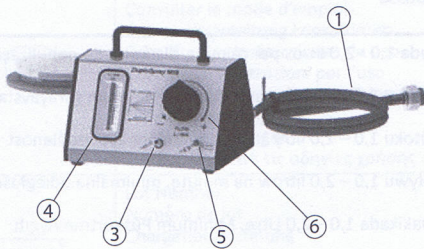
If flow is not verified:

- Immediately remove DUPLOSPRAY MIS Regulator from service.
- Call Baxter Customer Service using the contact information shown on the base of the device or contact your local Baxter representative.

4.0 STORAGE

Conditions:

- Ambient indoor 55°F (13°C) to 95°F (35°C), 0% to 95% RH continuous.



DUPLOSPRAY REGULATOR PARTS LIST

1	Gas Connection
2	Foot Switch
3	Patient Vent Connection
4	Flow Meter
5	Gas Outlet to Applicator
6	Gas Flow Control Knob
7	Pole Clamp
8	PN 0600134 - NIST B11 Connector US List Number 0600123